IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF VIRGINIA

NORFOLK DIVISION

G.D. SEARLE LLC and PFIZER ASIA PACIFIC PTE. LTD., Plaintiffs, v. LUPIN PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., MYLAN PHARMACEUTICALS INC., WATSON LABORATORIES, INC., APOTEX INC., and APOTEX CORP., Defendants.	CASE NO. C.A. 2:13-cv—0121-AWA-LRL

MEMORANDUM IN SUPPORT OF MYLAN'S MOTION FOR SUMMARY JUDGMENT OF PATENT INVALIDITY

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INTRODUCTION AND SUMMARY OF ARGUMENT

Defendant Mylan Pharmaceuticals Inc. ("Mylan") moves for summary judgment of invalidity against U.S. Reissued Patent No. RE44,048 E ("the '048 reissue patent") asserted by Plaintiffs G.D. Searle LLC and Pfizer Asia Pacific Pte. Ltd. (collectively "Pfizer").

Pfizer's '048 reissue patent is invalid like U.S. Patent No. 5,760,068 ("the '068 patent") from which it reissued. Pfizer litigated and lost on the original '068 patent. The Federal Circuit found that the '068 patent was invalid over an earlier Pfizer patent, U.S. Patent No. 5,563,165 ("the '165 patent"), because Pfizer had failed to take advantage of a statutory safe harbor under 35 USC § 121. *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353, 1360 (Fed. Cir. 2008). Pfizer responded to the Federal Circuit's mandate by instituting improper reissue proceedings in the United States Patent & Trademark Office ("Patent Office") in an attempt to secure an extra 18 months of patent term for its Celebrex® products.

The Patent Office resisted Pfizer's attempts to bring this patent back to life. For more than four years, Pfizer's lawyers came up with argument after new argument. Finally, after repeated interviews and lengthy legal briefs in the guise of replies to Office actions, the Patent Office's defenses had been worn down, and the Patent Office allowed a reissue to proceed in order to correct some alleged errors in the claims. Pfizer's lawyers took full advantage of the Patent Office's decision. Pfizer's lawyers did not, however, correct the claims as they had requested, but instead replaced the claims with new, different claims directed specifically to Pfizer's blockbuster Celebrex® franchise. And Pfizer's lawyers did not just change the claims; Pfizer's lawyers came up with an entirely new history for the patent which sought to exclude the intentional strategic choices Pfizer had made previously. Moreover, Pfizer's lawyers made substantial changes to the specification, stripping out some (but not all) of the text Pfizer had

intentionally added over the years. In addition, Pfizer's lawyers sought to change the patent from a "continuation-in-part" to a "divisional," in order to secure the safe harbor that the Federal Circuit had previously told Pfizer it had failed to secure.

The deficiencies in the '048 reissue patent are myriad. Among those deficiencies, and the basis for the instant motion, are the following: (1) the '048 reissue patent is not entitled to the § 121 safe harbor and therefore remains invalid over the '165 patent; (2) new matter was added rendering the reissue invalid under 35 U.S.C. § 251; and (3) the '048 reissue patent included a broadened claim rendering the reissue invalid similarly under 35 U.S.C. § 251. And each of those deficiencies is a basis for invalidating the patent. There are no genuine issues of material fact that would prevent the grant of summary judgment on any of these issues, and any one of them would invalidate the patent. Mylan respectfully requests that the Court grant Mylan's summary judgment motion and invalidate this reissue patent.

STATEMENT OF UNDISPUTED FACTS

The undisputed facts below, together with the governing law, compel the grant of Mylan's motion for summary judgment of patent invalidity.

Prosecution of the '594 Grandparent Application to the '068 Patent

1. On November 30, 1993, Pfizer filed U.S. Patent Application No. 08/160,594 ("the '594 application"), claiming compounds, pharmaceutical compositions, and methods of use. Exhibit 1 (the '594 application file history) at PFZCEDV_1246232 – 1246350 (the '594 application).

2. On July 12, 1994, the examiner issued a restriction requirement in the '594 application, which restricted the claims into compounds, compositions, and methods of use. The

'594 application file history at PFZCEDV_1246414 – 1246417 (July 12, 1994 Restriction Requirement).

Prosecution of the '629 Parent Application to the '068 Patent

3. On April 6, 1994, Pfizer filed U.S. Patent Application No. 08/223,629 ("the '629 application"), claiming compounds, pharmaceutical compositions, and methods of use. Exhibit 2 (the '629 application file history) at PFZCEDV_1247716 – 1247839 (the '629 application).

4. Pfizer filed the '629 application as a continuation-in-part ("CIP") of the '594 application. The '629 application file history at PFZCEDV_1247716 – 1247839 (the '629 application). The '629 application file history at PFZCEDV_12478389 (the April 6, 1994 preliminary amendment) ("This is a Continuation-In-Part application of application Serial No. 08/160,594 filed November 30, 1993."); Exhibit 4 (October 11, 2013 expert report of Joseph F. Dellaria, Jr., Ph.D. ("Dellaria Report")) at ¶ 52.

5. The '629 application added new subject matter not found in the '594 application. The '629 application file history at PFZCEDV_12478389 (the August 6, 1994 preliminary amendment); Exhibit 3 (Nov. 5, 2013 deposition of Philip Polster II ("Polster trans.")) at 44:16-18.

6. The '629 application could not have been designated as a divisional of the '594 application because of the additional subject matter added since the '594 application. Manual of Patent Examining Procedure ("MPEP") § 201.06; *see also* Polster trans. at 71:14-23; 72:9-14.

7. The '629 application was filed as a CIP of the '594 application **three months before** there was a restriction requirement directed to the '594 application. The '629 file history at PFZCEDV_1247716 – 1247839 (the '629 application); Exhibit 5 (the '068 patent) at

PFZCEDV_0739860; Polster trans. at 41:20-24; Exhibit 6 (October 11, 2013 expert report of Nancy Linck, Ph.D. ("Linck Report")) at ¶ 50.

8. The '629 application eventually issued as U.S. Patent No. 5,521,207 ("the '207 patent") with claims directed to a compound known as deracoxib. Exhibit 7 (the '207 patent) at PFH_0032448 – 0032471; Polster trans. at 44:16-45:11; Exhibit 8 (Approved Animal Drug Products ("Green Book")) Section 2.0 – Active Ingredients at 19; Green Book Section 3.0 – Patent Information at 3. The deracoxib compound was part of the new matter that was added to the '629 application when it was filed as a CIP. Polster trans. at 44:16-45:11.

9. The '207 patent is listed in the Food & Drug Administration's publication entitled Approved Animal Drug Products ("Green Book") as covering the animal drug product Deramaxx® Chewable Tablets. Green Book Section 3.0 – Patent Information at 3. The active ingredient in Deramaxx® Chewable Tablets is deracoxib. Green Book Section 2.0 – Active Ingredients at 19.

Prosecution of the Double Patenting Reference – the '165 Patent

10. On June 1, 1995, Pfizer filed U.S. Application No. 08/457059 ("the '059 application), claiming the pharmaceutical compositions restricted from the '594 application. Exhibit 9 (the '059 application) at PFZCEDV_1248645 - 1248791.

11. Pfizer filed the '059 application as a divisional application of the '594 application. The '059 application at PFZCEDV_1248773 ("This is a divisional of U.S. application 08/160,594, filed November 30, 1993."); PFZCEDV_1248769 ("Amend the specification by inserting before the first line the sentence: --This is a Divisional of application Serial No. 08/160,594 filed November 30, 1993.—").

12. The ’059 application issued as U.S. Patent No. 5,563,165 (“the ’165 patent”) claiming pharmaceutical compositions. Exhibit 10 (the ’165 patent) at PFH_0032541 - 0032547. Claim 5 of the ’165 patent claims compositions selected from compounds including celecoxib. The ’165 patent at PFH_0032543 – 0032544; Dellaria Report at ¶ 62. The ’165 patent discloses methods of using celecoxib. The ’165 patent at PFH_0032521 (“[Celecoxib] would be useful for the treatment of inflammation in a subject, and for treatment of other inflammation-associated disorders . . . .”). Dellaria Report at ¶ 63-64.

Prosecution of the International PCT Application Leading to the ’068 Patent

13. On November 10, 1994, Pfizer filed International Application No. PCT/US94/12720 (“the PCT application”), claiming compounds, pharmaceutical compositions, and methods of use. Exhibit 11 (the PCT application) at PFC01501498 – 1501500, PFZCEDV_1224188 – 1224195, PFC01499332 – 01499605, PFC015014 - 1501017 (PCT Transmittal Letter, Request, specification and claims as filed).

14. Pfizer filed the PCT application as a CIP of the ’629 application, claiming priority to the ’629 application which was a CIP of the ’594 application. Exhibit 12 (published PCT application) at PFZCEDV_1223912.

15. Pfizer added new matter to the PCT application. The PCT application at PFC01501498 – 1501500, PFZCEDV_1224188 – 1224195, PFC01499332 – 01499605, PFC015014 - 1501017 (PCT Transmittal Letter, Request, specification and claims as filed); Published PCT application at PFZCEDV_1223912; Polster trans. at 72:3-8; Dellaria Report at ¶¶ 55-56; Linck Report at ¶ 62.

16. There were no factual inaccuracies with the PCT application’s claim of priority. *See* Polster trans. at 27:12-29:24, 70:7-71:5.

17. The PCT application's claim of priority has not been changed. Polster trans. at 70:7-71:5; Exhibit 13 (November 13, 2013 deposition of Arthur Dean Olson ("Olson trans.")) at 85:19-86:12; Linck Report at ¶ 59, Exhibit 14 (MPEP 5th ed. Rev. 16 (March 1994) Appendix T titled Patent Cooperation Treaty ("PCT rules") at Rule 90 *bis*.3(a) (Withdrawal of International Application).

18. The PCT application could not have been designated as a divisional of the '594 application because of the additional subject matter added since the '594 application. PCT rules at T-30, Rule 4.14; MPEP § 201.06; Polster trans. at 72:9-14.

19. Pfizer prosecuted other applications that issued as patents, claiming priority to the PCT application as a CIP of the '629 and '594 applications and claiming subject matter that was added to the PCT application. *See* Dellaria Report at § VIII. For example, at least two of Pfizer's own patents, U.S. Patent No. 6,413,960 and U.S. Patent No. 6,942,411 claim priority to the PCT application as a CIP of the '629 and '594 applications, and claim subject matter that was added to the PCT application. *See* Dellaria Report at § VIII.

The PCT Application Enters the U.S. National Stage as the '113 Application

20. The PCT application entered the U.S. national stage as U.S. Patent Application No. 08/648,113 ("the '113 application") under 35 U.S.C. § 371(a) and was given a filing date of September 6, 1996. Exhibit 15 (the '113 application) at PFZCEDV_1194988 – 1195202. Exhibit 16 (Notification of Acceptance under 35 U.S.C. 371 from the file history of the '113 application) at PFC01560971.

21. Pfizer filed the '113 application as a CIP of the '629 application, which was a CIP of the '594 application. Exhibit 17 (October 10, 1996 preliminary amendment filed with the '113 application) at PFZCEDV_1194979. In addition, Pfizer added new subject matter not

included in the ’594 or the ’629 application by adding claim 22, which was directed towards a “method for the prevention of colorectal cancer.” October 10, 1996 preliminary amendment filed with the ’113 application at PFZCEDV_1194979.

22. The ’113 application could not have been designated as a divisional of the ’594 application because of the additional subject matter added since the ’594 application. MPEP § 201.06; *see also* Polster trans. at 72:9-14.

23. There were no factual inaccuracies in the claim of priority in the ’113 application. Polster trans. at 27:12-29:24, 70:7-71:5; Olson trans. at 46:15-23.

The ’113 Application Issued as the ’068 Patent

24. The ’113 application issued as U.S. Patent No. 5,760,068 (“the ’068 patent”). The ’068 patent at PFZCEDV_0739860 – 0739914.

25. The ’068 patent did not contain a claim to the treatment of menstrual cramps. The ’068 patent at PFZCEDV_0739909 – 0739914, 97:48 – 108:30.

26. The ’068 patent had independent claims directed to methods of treating inflammation or an inflammation-associated disorder. The ’068 patent at PFZCEDV_0739909, 97:48 – 98: 47 (claim 1 of the 068 patent); PFZCEDV_0739912 – 0739913, col. 104:63 – 105:32 (claim 6); PFZCEDV_0739913, 106:14 – 37 (claim 9); PFZCEDV_0739913 – 0739914, 106:46 – 107:13 (claim 11).

27. The ’068 patent had dependent claims where the inflammation-associated disorder is arthritis, pain, fever, or colorectal cancer. The ’068 patent at PFZCEDV_0739914, 108: 23-30 (claims 15-18).

The Federal Circuit Invalidated the '068 Patent for Obviousness-Type Double Patenting Over the '165 Patent

28. Pfizer[1] asserted the '068 patent, among other patents, against Teva Pharmaceuticals USA, Inc. ("Teva") in civil action no. 04-754 (JCL) (D.N.J.). Exhibit 18 (Complaint, *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 482 F. Supp. 2d 390 (D.N.J. 2007), (No. 04-754 (JCL)(MF)) at 6-8.

29. In civil action no. 04-754 (JCL) (D.N.J.), Pfizer asserted claims 1-4 and 11-17 of the '068 patent against Teva. Exhibit 19 (Final Pretrial Order, *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 482 F. Supp. 2d 390 (D.N.J. 2007) (No. 04-754 (JCL)(MF)) at 9.

30. In civil action no. 04-754 (JCL) (D.N.J), Pfizer submitted an expert report by Dr. James McGinity opining that the asserted claims of the '068 patent were definite. Exhibit 20 (June 22, 2006 expert report of James W. McGinity, Ph.D.) at PFH_0013948, PFH_0013964. These asserted claims included claims Pfizer later asserted were "indefinite" to support its reissue application.

31. The district court's decision in civil action no. 04-754 (JCL) (D.N.J) did not address the issue of indefiniteness. *See generally Pfizer*, 482 F. Supp. 2d at *passim*.

32. The district court's decision in civil action no. 04-754 (JCL) (D.N.J) found the '068 patent not invalid for obviousness-type double patenting. *Id.* at 477.

33. The district court's decision in civil action no. 04-754 (JCL) (D.N.J) did not consider Teva's argument that § 121 is not applicable to the '068 patent. *Id.* at 475-76.

34. Teva appealed the district court's decision in civil action no. 04-754 (JCL) (D.N.J), and in the Federal Circuit's decision dated March 7, 2008, the Federal Circuit concluded that: "(1) Pfizer cannot claim the protection of section 121 with respect to the '068 patent

[1] The plaintiffs in this action included Pfizer Inc., Pharmacia Corp., Pharmacia & Upjohn Inc., Pharmacia & Upjohn Company, G.D. Searle & Co., G.D. Searle LLC, Searle LLC (Delaware), and Searle LLC (Nevada).

because that patent did not issue on a divisional application, and (2) the asserted claims of the '068 patent are not patentably distinct from the claims of the '165 patent. Accordingly, the '068 patent is invalid for obviousness-type double patenting." *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008).

35. The Federal Circuit decision did not address the definiteness of the claims of the '068 patent. *See generally Pfizer Inc.*, 518 F.3d at *passim*.

Pfizer Sought the Reissue of the Invalidated '068 Patent through the '319 Reissue Application

36. On September 5, 2008, Pfizer filed U.S. Reissue Patent Application No. 12/205,319 ("the '319 application") to reissue the '068 patent. Exhibit 21 (Bulock Dep. Exhibit 1 ("the '319 application")).

37. Pfizer filed a preliminary amendment with the '319 application where Pfizer deleted the claim of priority to the '629 application, deleted references to the '113 application being a CIP, and added language claiming that the '113 application was a divisional of the '594 application. The '319 application at page 3.

38. In the preliminary amendment, Pfizer also made extensive amendments to the '068 patent specification, deleting a substantial amount of the material from the '068 patent. The '319 application at 3-22. In addition, Pfizer cancelled claims 2-12 and 18. The '319 application at pages 26-27.

39. In the reissue application declaration accompanying the preliminary amendment, Pfizer stated: "[a]t least one error upon which reissue is based is described as follows . . . . Applicant therefore is requesting reissue of U.S. Patent No. 5,760,068 to correct those errors that prevented the application from which the patent issued from complying with the definition of a divisional application pursuant to M.P.E.P. 201.06 entitled to protection under 35 U.S.C. § 121

as recently enunciated by the Federal Circuit." Exhibit 22 (Reissue Application Declaration Accompanying '319 application) at PFH_0000049.

40. On December 3, 2009, the examiner issued a non-final rejection of the '319 application, stating that the reissue declaration "fail[ed] to specifically identify an error. Failure to 'timely' file a divisional application prior to issuance of [the] original patent is not correctable in reissue under 35 U.S.C. 251." Exhibit 23 (December 3, 2009 non-final rejection) at PFH_0012327.

41. On September 22, 2010, the examiner issued a final rejection of the '319 application, maintaining that the reissue declaration was defective because "[f]ailure to 'timely' file a divisional application prior to the issuance of [the] original patent is not correctable in reissue under 35 U.S.C. § 251." Exhibit 24 (September 22, 2010 final rejection) at PFH_0025410. In the September 22, 2010 final rejection, the examiner also noted that claims 2-12 and 18 had been cancelled. September 22, 2010 final rejection at PFH_0025408.

42. On March 10, 2011, Pfizer filed a Request for Continued Examination ("RCE") of the '319 application with a second reissue declaration. Exhibit 25 (March 10, 2011 RCE) at PFH_0025429-PFH_0025442, PFH_0025446-PFH_0025447.

43. Along with the RCE, Pfizer submitted a new declaration stating that there were errors correctable by reissue in the invalidated '068 patent specifically that (1) claims 1-5, 13-18 were indefinite; and (2) claims 2, 3, 7, 8, and 12 were improper dependent claims. March 10, 2011 RCE at PFH_0025447 (Reissue Application Declaration Accompanying March 10, 2011 RCE).

44. Arthur Dean Olson, one of Pfizer's attorneys responsible for prosecuting the '319 application, stated that Pfizer identified these alleged errors only after "the previous[ly] asserted

error was rejected by the examiner." Olson trans. at 100:16-101:3. Specifically, Pfizer was "looking for an error that was correctable via re-issue." Olson trans. at 100:16-101:3.

45. The March 10, 2011 filing of the RCE is the first instance in the prosecution of the '319 application where Pfizer argued to the examiner that the claims in the invalidated '068 patent were indefinite. Olson trans. 99:25-101:3.

46. Pfizer did not revise or amend the alleged indefinite and improper dependent claims to address the alleged "errors." Exhibit 26 (July 19, 2011 Statement of Substance of the Interview) at PFH_0029304. These claims were cancelled. Instead, Pfizer sought to fix the alleged "error" the examiner had previously identified in multiple Office actions as not correctable through reissue by deleting the claim of priority to the '629 application, deleting references to the '113 application being a CIP, and adding language claiming that the '113 application was a divisional of the '594 application. March 10, 2011 RCE at PFH_0025438 - 0025439. In addition, Pfizer deleted a substantial amount of material to the specification – the same deletion that Pfizer sought in its original preliminary amendment filed in September 5, 2008, and that the examiner previously rejected in multiple Office actions as errors not correctable in reissue. March 10, 2011 RCE at PFH_0025440.

47. On July 10, 2012, the examiner withdrew the rejection based on a defective reissue declaration and allowed the reissue application because "it identifies at least one error." Exhibit 27 (Notice of Allowance) at PFH_0039421.

The '113 Application Matured into the '048 Reissue Patent with an Independent Claim Directed to a Method of Treating Menstrual Cramps & Five Compounds Not Present in the '594 Application

48. On March 5, 2013, the '113 application issued as the '048 reissue patent. Exhibit 28 (the '048 reissue patent) at PFZCEDV_1198024 – 1198104. The '048 reissue patent issued with the deletion of (1) the claim of priority to the '629 application, (2) references to the '068

patent being a CIP, including language claiming that the ’068 patent was a CIP of the ’594 application, and (3) a substantial amount of material from the specification from the ’068 patent. *Compare* the ’048 reissue patent at PFZCEDV_1198024 – 1198104 *with* the ’068 patent at PFZCEDV_0739860 – 0739914. All the claims from the ’048 reissue patent are directed toward method of treatment using celecoxib. The ’048 reissue patent at PFZCEDV_1198104.

49. The ’048 reissue patent issued with independent claim 25 directed to the treatment of menstrual cramps. The ’048 reissue patent at PFZCEDV_1198104, 110:52-57.

50. Both primary and secondary dysmenorrhea can cause menstrual cramps. Exhibit 29 (September 18, 2013 declaration of James A. Simon, M.D.) at ¶ 14; Exhibit 30 (October 11, 2013 expert report of Bruce R. Carr, M.D. (“Carr Report”)) at ¶ 17; Exhibit 31 (November 15, 2013 expert report of James A. Simon (“Simon Report”)) at ¶¶ 18-19.

51. There are menstrual cramps associated with secondary dysmenorrhea that are caused by a variety of pelvic diseases that are not inflammatory diseases. Carr Report at ¶¶ 24-27, 43-50; Simon Report at ¶¶ 27, 35. For example, polyps or fibroid tumors inside the uterine cavity (submucous) cause cramps by filling and expanding the cavity or otherwise obstructing outflow, resulting in menstrual cramps that are independent of inflammation. Carr Report at ¶ 46; Simon Report at ¶ 27.

52. There are menstrual cramps associated with secondary dysmenorrhea that are independent of pain associated with inflammation, including menstrual cramps caused by endometriosis, intramural or submucous myomas, intrauterine device, adenomyosis, endometrial polyps, and a blind uterine horn. Carr Report at ¶¶ 26, 46; Simon Report at ¶¶ 26-27, 35.

53. There are at least five compounds in the '048 reissue patent, Examples 153-156 and 160, which were not present in the '594 application. Dellaria Report at ¶¶ 65-79; Exhibit 32 (November 15, 2013 expert report of Robert J. Spar) at ¶¶ 150-155.

LEGAL ARGUMENT

I. Legal Standard for Summary Judgment

Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material facts and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). No genuine issue of material fact exists "[w]here the record taken as a whole could not lead a rational trier of fact to find for the non-moving party . . . ." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). Where, as here, no genuine issue of material fact exists, summary judgment should be granted.

Furthermore, "the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphasis in original). Instead, "[o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." *Id.* at 248. Summary judgment is as appropriate in a patent case as in any other. *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1576-77 (Fed. Cir. 1989).

II. The Claims of the '048 Are Not Entitled to the Safe Harbor, and Remain Invalid for Double-Patenting

Pfizer's '048 reissue patent is not entitled to the safe harbor of 35 U.S.C. § 121, and is therefore invalid over the '165 patent. "Obviousness-type double patenting is a judicially created doctrine that prohibits a party from obtaining an extension of the right to exclude through claims

in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." *Pfizer*, 518 F.3d at 1363 (internal citations and quotations omitted). The Federal Circuit has repeatedly held a "claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use." *Id.* (quoting *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1385-86 (Fed. Cir. 2003)). Obviousness-type double patenting is a question of law. *Id.*

35 U.S.C. § 121 provides a "safe harbor" against obviousness-type double patenting in certain limited circumstances. The "safe harbor" provision of 35 U.S.C. § 121 states in relevant part:

> A patent issuing on an application with respect to which a requirement for restriction[2] under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application[3] or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

The purpose of this "safe harbor" provision is to protect applications that were required to be divided from being used as obviousness-type double patenting references against one another. *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1350 (Fed. Cir. 2009). The § 121 safe harbor, however, only applies if each of the following requirements are met: (1) the application was filed as a divisional application; (2) the application was filed "as a result of" a restriction

[2] During the prosecution of a patent application, an examiner may determine an application contains two or more independent and distinct inventions. 37 C.F.R. § 1.142(a). If the examiner makes this determination, the examiner will issue a restriction requirement, which requires the applicant to select one invention for further prosecution, and the other unelected inventions are withdrawn from further examination. 37 C.F.R. §1.142(b). The applicant, however, can choose to pursue one or more of the other unelected inventions in a divisional patent application.

[3] A divisional application is defined by the Manual of Patent Examining Procedure ("MPEP") as "[a] later application for an independent or distinct invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application . . . ." MPEP § 201.06.

requirement made by the examiner; (3) the application was filed "before the issuance of the patent on the other application;" and (4) the divisional application claims the subject matter restricted by the examiner. *Pfizer*, 518 F.3d at 1359-60. The party seeking to invoke the protection of the § 121 safe harbor has the burden of showing that § 121 applies to the patent at issue. *See Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1381 (Fed. Cir. 2003).

A. The '048 Reissue Patent is Not Entitled to the § 121 Safe Harbor

The '048 reissue patent is not entitled to the protection of the § 121 safe harbor because neither of the first two *Pfizer* requirements were met. The '048 reissue patent was not the product of a divisional application, nor was the application that matured into the '048 reissue patent the result of a restriction requirement. Therefore, the '165 patent remains invalidating prior art to the '048 reissue patent. *See Pfizer*, 518 F.3d 1353, 1362 ("We hold that section 121 does not apply to the '068 patent and that the '165 patent may be used to invalidate the '068 patent.").

1. The Application that Matured Into the '048 Reissue Patent Was Not a Divisional

The application that matured into the '048 reissue patent was not a divisional application. The face of the '113 application and the face of the '068 patent confirm that fact. No amount of rewriting of the specification of the '068 patent in a later-filed reissue application changes the dispositive fact that the application resulting in the '068 patent was filed as a CIP of the '594 application and not a divisional. Both priority documents to the '068 patent – the '629 application and PCT application – were filed as CIPs. SOF ¶¶ 4, 6, 14, 18. Again, the later filing of a reissue application cannot alter these facts. Consequently, the '048 reissue patent does not fall within the § 121 safe harbor.

Pfizer filed the '113 application as a CIP because it included material not previously disclosed in an earlier patent application. SOF ¶¶ 21-22. A CIP, by definition, ***cannot*** be a divisional.[4] *See* MPEP § 201.06 ("While a divisional application may depart from the phraseology used in the parent application there may be no departure therefrom in substance or variation in the disclosure that would amount to 'new matter' if introduced by amendment into the parent application."); *see also Pfizer*, 518 F.3d at 1360 (quoting MPEP § 201.06). Because the application that led to the '048 reissue patent is not a divisional application and does not claim priority to a divisional application, it is not protected by the safe harbor. *Amgen*, 580 F.3d at 1354 ("Because the '178 and '179 applications were filed as continuation applications instead of divisional applications, we hold that the '933, '422, and '349 patents do not receive the protections afforded by § 121's safe harbor.").

Moreover, it is clear that Pfizer meant to take advantage of the filings of the '629 and PCT applications as CIPs. The patent that issued from the '629 application, U.S. Patent No. 5,521,207 ("the '207 patent"), claims the deracoxib compound that is currently marketed by Pfizer as the animal drug Deramaxx®. SOF ¶¶ 8-9; Green Book Section 2.0 – Active Ingredients at 19; Green Book Section 3.0 – Patent Information at 3. The deracoxib compound was part of the new matter that was added to the '629 application when it was filed as a CIP. SOF ¶ 8; Polster trans. at 44:16-45:11. Further, at least two of Pfizer's own patents – U.S. Patent No. 6,413,960 and U.S. Patent No. 6,492,411 – claim priority to the PCT application as a CIP of the '629 and '594 applications, and claim subject matter that was added to the PCT application.

[4] Even accepting Pfizer's revisionist prosecution history, the '048 patent still cannot be a divisional of the '594 application because it contains at least five compounds that are not present in the '594 application. *See infra* Section III.A.2. A divisional application cannot contain new matter. *Pfizer*, 518 F.3d at 1360; MPEP § 201.06.

SOF ¶ 19; *see* Dellaria Report § VIII. These patents take advantage of the CIP status of '629 and PCT applications, and belie Pfizer's attempt to rewrite the prosecution history.

Accordingly, the '165 patent is prior art to the '048 reissue patent.

2. The Application that Matured Into the '048 Reissue Patent Was Not the Result of a Restriction Requirement

None of the applications that led to the '048 reissue patent was filed as a result of a restriction requirement. That undisputed fact is dispositive because the statutory language is clear – in order to take refuge in the § 121 safe harbor, an application needs to be filed "as a result of" a restriction requirement. 35 U.S.C. § 121; *see also Pfizer*, 518 F.3d at 1362 ("We conclude that the protection afforded by section 121 to applications (or patents issued therefrom) **filed as a result of a restriction requirement** is limited to divisional applications.") (emphasis added).

The prosecution history is undisputed and unambiguous. The '629 application was filed **three months before** there was a restriction requirement, and added new matter. SOF ¶¶ 3, 5, 7. The PCT application claimed priority to the '629 application and added additional new matter. SOF ¶¶ 14-15. The '113 application claimed to be a national stage application of the PCT application and claimed priority to the '629 application. SOF ¶¶ 20-21. The '068 patent issued from the '113 application. SOF ¶¶ 24. None of the applications leading to the '068 patent was filed as a result of a restriction requirement, and the safe harbor does not apply to the reissue patent.

The safe harbor statute is clear and unambiguous – a divisional application needs to be filed "as a result of" a restriction requirement. 35 U.S.C. § 121. Yet, Pfizer is asking this Court to ignore this clear and unambiguous language in order to fall within the double patenting safe harbor. Just as the Federal Circuit did in *Pfizer v. Teva*, this Court should reject Pfizer's attempt

to reinterpret § 121. *See Pfizer*, 518 F.3d at 1360 ("In other words, Pfizer contends that the term 'divisional application' as it is used in § 121 refers broadly to any type of continuing application filed as a result of a restriction, regardless of whether it is labeled by the PTO, for administrative purposes, as a divisional, a continuation, or a CIP. We disagree.").

Accordingly, the '048 reissue patent is not protected by the safe harbor, and the '165 patent is prior art to the '048 reissue patent.

B. The '048 Reissue Patent is Invalid for Obviousness-Type Double Patenting

The claims of the '048 reissue patent are invalid for obviousness-type double patenting because they are not patentably distinct from the claims of the prior art '165 patent. *Pfizer*, 518 F.3d at 1363.

The '048 reissue patent purports to claim methods of using celecoxib, the active ingredient in Celebrex®. SOF ¶ 48. Claim 5 of the '165 patent claims compositions selected from a variety of compounds, including celecoxib. SOF ¶ 12; *see* the '165 patent at PFH_0032543-0032544; *see also Pfizer*, 518 F.3d at 1363. Each purported method claimed in the '048 reissue patent were taught in the prior art '165 patent, as shown below:

'048 Reissue Patent Claim	**Disclosure in '165 Patent**
Claim 19 of the '048 reissue patent claims "[a] method of treating arthritis in a subject . . . ."	The '165 patent states that that patent "relates to compounds, compositions and methods for treating inflammation and inflammation-associated disorders such as arthritis." '165 patent col. 1 ll. 13-15. The '165 patent further states that "compounds of Formula I would be useful to treat arthritis . . . ." '165 patent at col. 3 ll. 7-8. The '165 patent further states that "[t]he compounds are useful as anti-inflammatory agents, such as for the treatment of arthritis . . . ." '165 patent col. 3 ll. 24-25.

'048 Reissue Patent Claim	**Disclosure in '165 Patent**
	The '165 patent further states that "[t]he present invention comprises a pharmaceutical composition for the treatment of inflammation and inflammation-associated disorders, such as arthritis . . . ." '165 patent col. 18 ll. 31-33.
Claim 20 of the '048 reissue patent claims "[a] method of treating pain in a subject . . . ."	The '165 patent states that "compounds of Formula I would be useful to treat arthritis, including but not limited to rheumatoid arthritis, spondyloarthopathies, gouty arthritis, systemic lupus erythematosus, osteoarthritis and juvenile arthritis." '165 patent col. 3 ll. 7-11.
Claim 21 of the '048 reissue patent claims "[a] method of treating osteoarthritis in a subject . . . ."	The '165 patent states that "compounds of Formula I would be useful to treat arthritis, including but not limited to rheumatoid arthritis, spondyloarthopathies, gouty arthritis, systemic lupus erythematosus, osteoarthritis and juvenile arthritis." '165 patent col. 3 ll. 7-11.
Claim 22 of the '048 reissue patent claims "[a] method of treating rheumatoid arthritis in a subject . . . ."	The '165 patent states that "compounds of Formula I would be useful to treat arthritis, including but not limited to rheumatoid arthritis, spondyloarthopathies, gouty arthritis, systemic lupus erythematosus, osteoarthritis and juvenile arthritis." '165 patent col. 3 ll. 7-11.
Claim 23 of the '048 reissue patent claims "[a] method of treating juvenile arthritis in a subject . . . ."	The '165 patent states that "compounds of Formula I would be useful to treat arthritis, including but not limited to rheumatoid arthritis, spondyloarthopathies, gouty arthritis, systemic lupus erythematosus, osteoarthritis and juvenile arthritis." '165 patent col. 3 ll. 7-11.
Claim 24 of the '048 reissue patent claims "[a] method of treating spondyloarthropathy in a subject . . . ."	The '165 patent states that "compounds of Formula I would be useful to treat arthritis, including but not limited to rheumatoid arthritis, spondyloarthopathies, gouty arthritis, systemic lupus erythematosus, osteoarthritis and juvenile arthritis." '165 patent col. 3 ll. 7-11.
Claim 25 of the '048 reissue patent claims "[a] method of treating menstrual cramps in a subject . . . ."	The '165 patent states that "compounds of Formula I would be useful in the treatment of . . . menstrual cramps . . . ." '165 patent col. 3 ll. 11-14.

SOF ¶ 12; *see* the ’165 patent at PFH_0032520, 0032521, 0032528; the ’048 reissue patent at PFZCEDV_1198104.

Because the prior art ’165 patent taught the methods claimed in the ’048 reissue patent, the claims of the ’048 reissue patent are invalid for obviousness type double patenting. *See Pfizer*, 518 F.3d at 1363 (“the asserted claims of the ’068 patent are not patentably distinct from the claims of the ’165 patent. Accordingly, the ’068 patent is invalid for obviousness-type double patenting.”); *see also* Dellaria Report § V.

III. Inclusion of New Matter and a Broadened Claim Render the ’048 Reissue Patent Invalid Under 35 U.S.C. § 251

Pfizer opted to include new matter in its ’048 reissue patent and included a claim that is broader than the claims of the original ’068 patent. Each of these undisputable facts renders the ’048 reissue patent invalid under the patent reissue statute.

Reissue is “based on fundamental principles of equity and fairness….” *In re Weiler*, 790 F.2d 1576, 1579 (Fed. Cir. 1986), *quoted in In re Serenkin*, 479 F.3d 1359, 1362 (Fed. Cir. 2007). 35 U.S.C. § 251 allows for the reissuance of a patent when there is an “error” in the patent. Section 251, however, was neither enacted “as a panacea for all patent prosecution problems, nor as a grant to the patentee of a second opportunity to prosecute *de novo* his original application.” *In re Weiler*, 790 F.2d 1576, 1582 (Fed. Cir. 1986). The “error” required for reissue is limited to act of inadvertence, accident, and mistake – an “error” under § 251 does not include knowing choices made during prosecution. *In re Serenkin*, 479 F.3d at 1365; *In re Mead*, 581 F.2d 251, 256-57 (C.C.P.A. 1978); *see also In re Weiler*, 790 F.2d at 1583 n.4. Failure to file a divisional application is not correctable on reissue. *In re Watkinson*, 900 F.2d 230, 231-33 (Fed. Cir. 1990); *In re Orita*, 550 F.2d 1277, 1280 (C.C.P.A. 1977); MPEP § 1402.

Whether or not an applicant satisfied the reissue requirements of 35 U.S.C. § 251 is a matter of law. *In re Serenkin*, 479 F.3d at 1361.

A. The '048 Reissue Patent is an Invalid Reissue

Mylan's instant motion is limited to two of the many reasons why the '048 reissue patent is an invalid reissue. First, the '048 reissue patent issued with a claim broader than any of the claims of the '068 patent. *See* 35 U.S.C. § 251; *Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998). Second, new matter was added to the specification of the '048 reissue patent. *See* 35 U.S.C. § 251 ("No new matter shall be introduced into the application for reissue."); MPEP § 1411.02. Either one of these reasons renders the '048 reissue invalid.

1. The Reissue Patent is Invalid Because a Claim was Broadened More than Two Years After the Original Patent Issued

Claims in a reissue application may not be broadened more than two years after the original patent issued. 35 U.S.C. § 251; MPEP § 1412.03. A claim is broadened under § 251 if it is broader in scope in any way. *In re Bennett*, 766 F.2d 524, 526 (Fed. Cir. 1985) (en banc). Here, it is undisputed claim 25 of the '048 reissue patent is broader in scope than any of issued claims in the '068 patent, and therefore the '048 reissue patent is invalid.

The '068 patent did not contain a claim for the treatment of menstrual cramps, but did have independent claims directed to methods for treating inflammation or an inflammation-associated disorder. SOF ¶¶ 25-26. The '068 patent had dependent claims where the inflammation-associated disorder is arthritis, pain, fever, or colorectal cancer. SOF ¶ 27. The '048 reissue patent, however, has independent claim 25, which is directed to the treatment of menstrual cramps. SOF ¶ 49. This claim is broader in scope than any of the claims in the '068 patent because the treatment of menstrual cramps extends beyond the treatment of inflammation associated with such cramps and beyond the treatment of pain caused by inflammation.

Mylan's and Pfizer's experts agree that both primary and secondary dysmenorrhea can cause menstrual cramps. SOF ¶ 50. Mylan's and Pfizer's experts agree that there are menstrual cramps associated with secondary dysmenorrhea caused by a variety of pelvic diseases that are not inflammatory diseases. SOF ¶ 51. For example, polyps or fibroid tumors inside the uterine cavity (submucous) cause cramps by filling and expanding the cavity or otherwise obstructing outflow, resulting in menstrual cramps independent of inflammation. SOF ¶ 51. Mylan's and Pfizer's experts agree that there are menstrual cramps associated with secondary dysmenorrhea independent of pain associated with inflammation. SOF ¶ 52.

There is no battle of the experts on this issue. Both Mylan's and Pfizer's experts agree that menstrual cramps – particularly secondary dysmenorrhea – are broader than inflammation alone or pain alone. This is especially true because the claim directed to menstrual cramps in the '048 reissue is an independent claim. Claim 25 of the '048 reissue patent is broader than the claims of the '068 patent and was filed more than two years after the issuance of the '068 patent – the period during which the claims could have been broadened. Therefore, the '048 reissue patent is an invalid reissue.

2. The Reissue Patent is Invalid Because New Matter was Added

The '048 reissue patent contains new matter as compared to the '594 application. The '594 application is the grandparent of the invalidated '068 patent, and the parent of the prior art '165 patent. Pfizer claims that the '048 reissue patent has the same specification as the '594 application and therefore can claim to be a divisional of the '594 application, entitled to refuge in the double patenting safe harbor from the '165 patent. See SOF ¶¶ 38-39. There are, however, at least five compounds in the '048 reissue patent, Examples 153-156 and 160, which were not present in the '594 application. SOF ¶ 53. In fact, Pfizer's own expert, while arguing that it was a "typographical error[]," admits that these compounds were not present in the '594 application,

but are present in the '048 reissue patent. SOF ¶ 53; *see* Spar Report at ¶¶ 150-155. Yet, new matter is not allowed in a reissue application – it is irrelevant how the new matter arrived in the reissue application. 35 U.S.C. § 251; MPEP § 1411.02. Given Pfizer is claiming the specification corresponds to the specification of the '594 application, the new matter contained in the '048 reissue patent invalidates the reissue. 35 U.S.C. § 251; MPEP § 1411.02; *e.g.*, *In re Hay*, 534 F.2d 917, 919 (C.C.P.A. 1976).

Furthermore, because of the new matter added to the reissue application and maintained in the '048 reissue, the '048 reissue patent cannot be a divisional of the '594 application. MPEP § 201.06. The new matter makes the '048 reissue patent an invalid reissue patent. Even if it were a valid reissue, the '048 reissue patent would not be characterized as a divisional and thus would not be entitled to the protections of the safe harbor.

CONCLUSION

Several dispositive grounds invalidate the '048 reissue patent: (1) the '048 reissue patent is not entitled to the § 121 safe harbor; (2) new matter was added to it; and (3) the '048 reissue patent impermissibly included a broadened claim. There are no genuine issues of material fact that would prevent the grant of summary judgment on any of these issues, and each of them invalidates the patent. Accordingly, Mylan respectfully asks the Court to grant its motion for summary judgment, dismiss this action with prejudice as to it, and award it its taxable costs.

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By counsel

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CERTIFICATE OF SERVICE

I hereby certify that on November 22, 2013, a true and correct copy of the foregoing was filed electronically using the CM/ECF system. As such, this document was served on all counsel who have consented to electronic service, including as follows:

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